

JAN 23 2012

K113661

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, Address, and Contact

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Contact: Bernice Lin, Ph.D.
VP Operations

Device Name and Classification

Classification Name: Methamphetamine Test System
Class II, LAF (91 Toxicology),
21 CFR 862.3610

Drug Specific Calibrators,
Class II, DLJ (91 Toxicology),
21 CFR 862.3200

Drug Specific Controls,
Class I, LAS (91 Toxicology),
21 CFR 862.3280

Common Name: Homogeneous Methamphetamine Enzyme Immunoassay
Proprietary Name: LZI Methamphetamine Enzyme Immunoassay,
LZI Methamphetamine Drugs of Abuse (DAU) Calibrators
LZI Methamphetamine Drugs of Abuse (DAU) Controls

Legally Marketed Predicate Device(s)

The LZI Methamphetamine Enzyme Immunoassay (EIA) at a cutoff of 500 ng/mL is substantially equivalent to the Amphetamines 500 Enzyme Immunoassay and Amphetamine 500 Calibrators and Controls for Hitachi 717 Systems (k102210) manufactured by Lin-Zh International, Inc with a cutoff of 500 ng/mL. The LZI Methamphetamine Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle device components, and clinical performance.

Device Description

The LZI Methamphetamine Enzyme Immunoassay is a homogeneous enzyme immunoassay with ready-to-use liquid reagent. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, methamphetamine-labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody would bind to free drug, the unbound methamphetamine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

The LZI Methamphetamine Enzyme Immunoassay is a kit comprised of two reagents, an R₁ and R₂ which are bottled separately but sold together within the kit.

The R₁ solution contains mouse monoclonal anti-methamphetamine antibody, glucose-6-phosphate (G6P) nicotinamide adenine dinucleotide (NAD), stabilizers, and sodium azide (0.09%) as a preservative. The R₂ solution contains glucose-6-phosphate dehydrogenase (G6PDH) labeled with d-methamphetamine in buffer with sodium azide (0.09%) as a preservative.

The LZI Methamphetamine Enzyme Immunoassay calibrators and controls designated for use at the 500 ng/mL cutoff contain 0, 250, 375, 500, 625, 1000, and 2000 ng/mL of d-methamphetamine in human urine with sodium azide (0.09%) as preservative. These five calibrators and two controls are sold as individual bottles.

Intended Use

The LZI Methamphetamine Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of d-methamphetamine in human urine, at a cutoff value of 500 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The semi-quantitative mode is for purposes of (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GCMS and LCMS or (2) permitting laboratories to establish quality control procedures.

The LZI Methamphetamine Drugs of Abuse (DAU) Calibrators are for use as calibrators in the qualitative and semi-quantitative calibration of the Methamphetamine Enzyme Immunoassay at a cutoff value of 500 ng/mL.

The LZI Methamphetamine Drugs of Abuse (DAU) Controls are for use as assayed quality control materials to monitor the precision of the Methamphetamine Enzyme Immunoassay at a cutoff value of 500 ng/mL.

The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method). Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

Comparison to Predicate Device

The Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay used at the 500 ng/mL cutoff is substantially equivalent to the Lin-Zhi International, Inc. Amphetamines 500 Enzyme Immunoassay, Calibrators and Controls for Hitachi 717 Systems cleared by the FDA under the premarket notification k102210 for its stated intended use.

The following table compares LZI's Methamphetamine Enzyme Immunoassay at the 500 ng/mL cutoff with the predicate device.

Device Characteristics	Subject Device LZI Methamphetamine Enzyme Immunoassay	Predicate Device (k102210) Amphetamines 500 Enzyme Immunoassay, Calibrators and Controls
Intended Use	<p>The LZI Methamphetamine Enzyme Immunoassay, when used in conjunction with Hitachi 717 automated clinical system analyzers, is intended for the qualitative and semi-quantitative determination of methamphetamine in human urine, at a cutoff value of 500 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers.</p> <p><i>This assay provides a rapid screening procedure for determining the presence of d-methamphetamine in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.</i></p>	<p>The Amphetamines 500 Enzyme Immunoassay from Lin-Zhi International, Inc., when used in conjunction with Hitachi 717 automated clinical system analyzers is intended for the qualitative and semi-quantitative determination of amphetamine and methamphetamine in human urine, at a cutoff value of 500 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers.</p> <p><i>This assay provides a rapid screening procedure for determining the presence of d-methamphetamine and d-amphetamine in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.</i></p>
Analyte	d-methamphetamine	d-methamphetamine & d-amphetamine
Cutoff	500 ng/ml	500 ng/mL
Matrix	Urine	Urine
Calibrators Level	5 Levels (0, 250, 500, 1000, 2000 ng/mL)	5 Levels (0, 250, 500, 1000, 2000 ng/mL)
Controls Level	2 Levels (375 ng/mL, 625 ng/mL)	2 Levels (375 ng/mL, 625 ng/mL)
Storage	2-8 °C until expiration date	2-8 °C until expiration date

Performance Characteristics Summary:
Hitachi 717 Analyzer

Precision:

Precision: Semi-Quantitative, ng/mL

N=88 (ng/mL)	Within Run			Total Precision		
	Mean	SD	% CV	Mean	SD	% CV
0 ng/mL	6.0	4.82	87.5%	6.0	5.5	91.6%
125 ng/mL	112.3	2.74	2.4%	112.3	4.0	3.6%
250 ng/mL	249.6	2.79	1.1%	249.6	4.6	1.9%
375 ng/mL	387.1	4.57	1.2%	387.1	5.4	1.4%
500 ng/mL	513.5	6.05	1.2%	513.5	8.3	1.6%
625 ng/mL	635.6	7.47	1.2%	635.6	9.6	1.5%
750 ng/mL	751.0	8.14	1.1%	751.0	12.1	1.6%
875 ng/mL	868.4	11.90	1.4%	868.4	14.9	1.7%
1000 ng/mL	987.7	11.25	1.1%	987.7	15.2	1.5%

Semi-Quantitative Precision Analysis Summary: Qualitative Results

N=88 (ng/mL)	Within Run		Total Precision	
	Mean	Qualitative Response	Mean	Qualitative Response
0 ng/mL	6.0	-	6.0	-
125 ng/mL	112.3	-	112.3	-
250 ng/mL	249.6	-	249.6	-
375 ng/mL	387.1	-	387.1	-
500 ng/mL	513.5	+	513.5	+
625 ng/mL	635.6	+	635.6	+
750 ng/mL	751.0	+	751.0	+
875 ng/mL	868.4	+	868.4	+
1000 ng/mL	987.7	+	987.7	+

Semi-Quantitative Positive/Negative Results:

500 ng/mL Cutoff Result:		Within Run		Total Precision	
Sample Concentration	% of Cutoff	Number of Determination	Immunoassay Result	Number of Determination	Immunoassay Result
0 ng/mL	-100.0%	22	22 Negative	88	88 Negative
125 ng/mL	-75.0%	22	22 Negative	88	88 Negative
250 ng/mL	-50.0%	22	22 Negative	88	88 Negative
375 ng/mL	-25.0%	22	22 Negative	88	88 Negative
500 ng/mL	0%	22	22 Positive	88	85 Pos/ 3 Neg
625 ng/mL	+25.0%	22	22 Positive	88	88 Positive
750 ng/mL	+50.0%	22	22 Positive	88	88 Positive
875 ng/mL	+75.0%	22	22 Positive	88	88 Positive
1000 ng/mL	+100.0%	22	22 Positive	88	88 Positive

Performance Characteristics Summary: continued

Hitachi 717 Analyzer

Precision: Qualitative, mA/min

N=88 (mA/min)	Within Run			Total Precision		
	Mean	SD	% CV	Mean	SD	% CV
0 ng/mL	92.6	0.7	0.7%	92.6	1.0	1.1%
125 ng/mL	122.1	0.7	0.6%	122.1	1.0	0.8%
250 ng/mL	167.2	1.0	0.6%	167.2	1.4	0.8%
375 ng/mL	210.0	1.1	0.5%	210.0	1.6	0.8%
500 ng/mL	244.9	1.3	0.6%	244.9	1.9	0.8%
625 ng/mL	273.5	1.5	0.6%	273.5	2.2	0.8%
750 ng/mL	296.5	2.2	0.7%	296.5	2.5	0.9%
875 ng/mL	318.1	1.8	0.6%	318.1	2.4	0.7%
1000 ng/mL	336.5	2.1	0.6%	336.5	3.0	0.9%

Qualitative Positive/Negative Results:

500 ng/mL Cutoff Result:		Within Run		Total Precision	
Sample Concentration	% of Cutoff	Number of Determination	Immunoassay Result	Number of Determination	Immunoassay Result
0 ng/mL	-100.0%	22	22 Negative	88	88 Negative
125 ng/mL	-75.0%	22	22 Negative	88	88 Negative
250 ng/mL	-50.0%	22	22 Negative	88	88 Negative
375 ng/mL	-25.0%	22	22 Negative	88	88 Negative
500 ng/mL	0%	22	16 Pos/6 Neg	88	62 Pos/26 Neg
625 ng/mL	+25.0%	22	22 Positive	88	88 Positive
750 ng/mL	+50.0%	22	22 Positive	88	88 Positive
875 ng/mL	+75.0%	22	22 Positive	88	88 Positive
1000 ng/mL	+100.0%	22	22 Positive	88	88 Positive

Limit of Detection:

The lowest concentration that can be differentiated from the negative urine with 95% confidence is determined as 25 ng/mL.

Linearity:

Hitachi 717 Instrument: 0 - 2000 ng/mL

When comparing the result (y) and target (x) value, using the least squares regression technique, the regression equation and correlation are as follow:

$$y = 0.9791x - 2.8289, r^2 = 0.9996$$

Method Comparison - Clinical Samples:

From a total of ninety-five (95) clinical unaltered samples

Semi-Quantitative Data:

97.87% agreement with positive,

100% agreement with negative samples

Qualitative Data:

97.87% agreement with positive,

100% agreement with negative samples

Performance Characteristics Summary: continued
Hitachi 717 Analyzer

Endogenous Compound Interference & Specificity & Cross-Reactivity:

No significant undesired cross reactants or endogenous substance interference was observed.

Summary:

The information provided in this pre-market notification demonstrates that the LZI Methamphetamine Enzyme Immunoassay at a cutoff value of 500 ng/mL is substantially equivalent to the legally marketed predicate device for its general intended use. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device as confirmed by chromatography/mass spectrometry (GC/MS or LC/MS), an independent analytical method. The information supplied in this pre-market notification provides reasonable assurance that the LZI Methamphetamine Enzyme Immunoassay at a cutoff value of 500 ng/mL is safe and effective for its stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

JAN 23 2012

Lin-Zhi International, Inc
c/o Dr. Bernice Lin
VP Operations
670 Almanor Avenue
Sunnyvale, CA 94085

Re: k113661
Trade Name: LZI Methamphetamine Enzyme Immunoassay
Regulation Number: 21 CFR §862.3610
Regulation Name: Methamphetamine Test System
Regulatory Class: Class II
Product Codes: LAF, DLJ, LAS
Dated: December 12, 2011
Received: December 13, 2011

Dear Dr Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Premarket Notification

Indications for Use Statement

510(k) Number (if known): k113661

Device Name: **LZI Methamphetamine Enzyme Immunoassay**
LZI Methamphetamine Calibrators and Controls

Indications for Use:

The LZI Methamphetamine Enzyme Immunoassay is intended for the qualitative and semiquantitative determination of d-methamphetamine in human urine, at the cutoff value of 500 ng/mL. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

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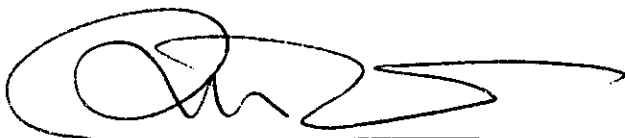
Prescription Use √
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k113661